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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH
CENTRAL DIVISION

UNITED STATES OF AMERICA and the STATE OF NEVADA *ex rel.* MICHAEL D. KHOURY, M.D.,

Plaintiffs,

v.

INTERMOUNTAIN HEALTHCARE, INC. d/b/a INTERMOUNTAIN HEALTHCARE; IHC HEALTH SERVICES, INC; MOUNTAIN WEST ANESTHESIA, LLC; DAVID A. DEBENHAM, M.D.; ERIC A. EVANS, M.D.; JOSHUA J. LARSON, M.D.; JOHN E. MINER, M.D.; TYLER W. NELSON, M.D.; and DOE ANESTHESIOLOGISTS 1 through 150,

Defendants.

Civil Case No. 2:20-cv-00372-TC-CMR

MOUNTAIN WEST ANESTHESIA, LLC AND PHYSICIAN DEFENDANTS' MOTION TO DISMISS

Judge Tena Campbell
Magistrate Judge Cecilia M. Romero

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Mountain West Anesthesia, LLC ("MWA"), David A. Debenham, M.D., Eric A. Evans, M.D., Joshua J. Larson, M.D., John E. Miner, M.D., and Tyler W. Nelson, M.D. (collectively, the "Physician Defendants") respectfully file this Motion to Dismiss the First Amended Complaint ("FAC") filed by Relator Michael D. Khoury, M.D. For the reasons stated below, these Defendants respectfully request that the Court dismiss with prejudice all of the claims asserted in the FAC.

PRELIMINARY STATEMENT

The Relator in this False Claims Act ("FCA") *qui tam* lawsuit alleges that MWA and its anesthesiologists, including the Physician Defendants, failed to provide otherwise necessary anesthesiology services in line with professional standards because they were distracted in the operating room by cell phones, tablets, and other personal electronic devices. Had any patient suffered an injury as a result, those allegations might well plead a state-law claim for medical malpractice. They do not, however, plead a federal fraud claim under the FCA. As Relator conceives the law, essentially every malpractice case involving a federal healthcare beneficiary would now become a federal FCA case with treble damages and a sizeable bounty available to any member of the public, simply because services that might have fallen below an articulated standard of care were billed to the government. No court has held that to be the law, and Relator's FAC offers no sound basis for why this Court should become the first.

Relator's allegations also suffer from many other flaws that compel dismissal. While Relator bases his theory of false claims on alleged violations of various Medicare and Medicaid regulations, he misinterprets those regulations, which provide no support for the falsity element of any FCA claim. And, even if the Defendants' alleged conduct *did* violate some regulation, Relator has not adequately pleaded that any such violations were material to payment. The FAC likewise lacks sufficient allegations to show that any defendant acted with the requisite scienter. Finally,

the FAC's allegations do not plead fraud with the particularity required by Federal Rule of Civil Procedure 9(b). That is because Relator has not adequately pleaded the specific details of any underlying fraud scheme or provided enough information to identify representative claims submitted or caused to be submitted by MWA or the Physician Defendants to the government.

For the foregoing reasons, Relator's FCA claims against MWA and the Physician Defendants should be dismissed with prejudice.

BACKGROUND

I. The Parties

MWA is an anesthesiology group medical practice based in Utah. (FAC ¶ 29.) MWA employs roughly 150 anesthesiologists who provide anesthesia services at hospitals and other medical facilities throughout the state. (*Id.*) The five Physician Defendants are board-certified anesthesiologists employed (or formerly employed) by MWA. (*Id.* ¶¶ 30-31.) According to Relator, each of the Physician Defendants has provided anesthesiology services at Dixie Regional Medical Center ("DRMC," now known as St. George Regional Hospital) in St. George, Utah, a hospital owned by Defendant IHC Health Services, Inc. (*Id.* ¶¶ 25-26, 31.)

The Relator in this action, Dr. Michael Khoury, is a vascular surgeon who performed surgical procedures at DRMC. (*Id.* ¶ 16.) Many of the surgical procedures Relator performed required patients to undergo general anesthesia. (*Id.*) According to Relator, the anesthesia services for at least some of these procedures were provided by the Physician Defendants or other MWA anesthesiologists, and Relator alleges MWA billed government healthcare programs or other third-party payors for these services. (*Id.* ¶¶ 17, 23, 33.) Relator is not affiliated with MWA and does not claim to have any personal knowledge of its billing practices or procedures.

II. Procedural History

Relator filed his original *qui tam* complaint in June 2020, asserting fraud claims on behalf of the United States and the state of Nevada. Relator filed his complaint under seal, and it remained under seal for roughly nine months to allow for any government investigation of the allegations. *See* 31 U.S.C. § 3730(b); Nev. Rev. Stat. Ann. § 357.080(4). In March 2021, the United States notified the Court that it would not intervene on any of Relator's claims. Despite the government's declination, Relator has chosen to litigate this action on the government's behalf.

III. Relator's Allegations

Relator's basic factual allegations are relatively straightforward. The FAC alleges that over a period of more than ten years, the Physician Defendants and unnamed MWA anesthesiologists routinely used cell phones, tablets, laptops, and other personal electronic devices ("PEDs") to attend to personal matters during surgeries at DRMC, which Relator contends prevented them from devoting their full attention to their professional duties. In Relator's opinion, the fact that the physicians were "distracted" in the operating room means that the anesthesiology services they provided were not billable to federal healthcare programs. Because MWA billed the services anyway, Relator contends, MWA and the Physician Defendants committed fraud and violated the FCA by submitting false claims to government healthcare programs.

Relator's legal conclusion that the anesthesiology services in question should not have been billed to federal healthcare programs is not based on any statute, regulation, or sub-regulatory guidance addressing "distractions" in the operating room. That is because none exist. Instead, Relator would have the Court divine such a rule from far more general requirements and guidelines, such as the broad principle that federal healthcare programs cover only "reasonable

and necessary" services, and the requirement that billable anesthesia services must be "continuous." But, Relator does not dispute that anesthesia was a necessary treatment in any particular surgery. Nor does Relator allege that any government healthcare beneficiary did not actually receive the anesthesia they needed, or that the Physician Defendants were not continuously present in the operating room during the relevant procedures. And the FAC never alleges that any patient ever suffered harm resulting from any of the Defendants' alleged conduct.

In essence, Relator contends that because the necessary anesthesia services the Physician Defendants *did* provide were not rendered in complete conformity with best surgical practices or applicable industry and professional society guidelines—or perhaps even Relator's own opinion—MWA's bills to federal healthcare programs for those services were *per se* fraudulent. This is a novel theory of fraud; Relator's FAC points to no past court decisions, enforcement actions, or regulatory guidance that would endorse such a theory of FCA liability under the facts pleaded here.

STANDARD OF REVIEW

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted). A claim is plausible only "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* If a complaint "pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Id.* (internal quotation marks omitted).

Fraud claims, including FCA claims, must satisfy the heightened pleading standard of Rule 9(b), which requires a plaintiff to "state with particularity the circumstances constituting fraud."

Fed. R. Civ. P. 9(b). The relator must "set forth the time, place, and contents of the false representation, the identity of the party making the false statements and the consequences thereof." *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006) (abrogated on other grounds). "At a minimum, Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." *Id.* at 726-27 (internal quotation marks omitted).

ARGUMENT

To prove his FCA claims, Relator must establish: "(1) a false statement or fraudulent course of conduct; (2) made with the requisite scienter; (3) that is material; and (4) that results in a claim to the Government." *U.S. ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 539 (10th Cir. 2020). The FAC fails to plausibly plead *any* of these elements.[1]

I. Relator Fails to Plead the Falsity Element of Any FCA Claim.

The FAC first fails to plausibly allege that MWA or the Physician Defendants submitted or caused to be submitted any *false* claim for payment to the government. As the Supreme Court has cautioned, the FCA is not "a vehicle for punishing garden-variety … regulatory violations." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016). Instead, the FCA applies only to *misrepresentations* material to payment, which requires a false or fraudulent claim. *See Sikkenga*, 472 F.3d at 727 ("[P]resentation of a false or fraudulent claim to the government is a central element of every [FCA] case.").

[1] Relator also has asserted claims under the Nevada False Claims Act, Nev. Rev. Stat. Ann. § 357.040, which is virtually identical to the federal FCA and interpreted in the same way. *See U.S. ex rel. Welch v. My Left Foot Child.'s Therapy, LLC*, 2017 WL 1902159, at *4 n.8 (D. Nev. May 9, 2017) (unpublished). Relator's state-law claims should be dismissed for the same reasons as his federal claims.

False or fraudulent claims include "both factually false and legally false requests for payment." *U.S. ex rel. Polukoff v. St. Mark's Hosp.,* 895 F.3d 730, 741 (10th Cir. 2018). "Factually false claims generally require a showing that the payee has submitted an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.* "Claims arising from legally false requests, on the other hand, generally require knowingly false certification of compliance with a regulation or contractual provision as a condition of payment." *Id.* Some courts recognize a theory of falsity based on a defendant's submission of bills to the government for "worthless services." *See, e.g.*, *U.S. ex rel. Hernandez-Gil v. Dental Dreams, LLC*, 2016 WL 9777254, at *9 (D.N.M. Sep. 26, 2016) (unpublished). Relator's allegations do not plead a plausible FCA claim under any theory of falsity.

A. The FAC's Allegations Do Not Plead a Plausible Theory of Factual Falsity.

Relator alleges that MWA's claims for payment to federal healthcare programs were factually false for two reasons. First, citing 42 C.F.R. § 414.46, Relator alleges that the Physician Defendants and other MWA anesthesiologists overstated the amount of "anesthesia time" they provided to federal healthcare beneficiaries, and that those false statements were incorporated into claims for reimbursement. (*See* FAC ¶¶ 8-10, 188–92.) Second, Relator contends that the Physician Defendants and other MWA anesthesiologists did not "personally provide" the anesthesia services at issue.[2] (*Id.*) Both theories of falsity fail because they misapprehend the

[2] Relator also argues that MWA and the Physician Defendants submitted factually false claims because the anesthesia services at issue were allegedly not "reasonable and necessary." (*See* FAC ¶¶ 185–86.) But, because the FAC does not allege that MWA and the Physician Defendants ever specifically certified that these services were reasonable and necessary, this is better understood as a theory of legal falsity. *See Polukoff,* 895 F.3d at 741. Regardless of the label used, Relator's position on this issue fails for the reasons stated below.

governing regulations.

The FAC alleges that the Physician Defendants and other MWA anesthesiologists overbilled for "anesthesia time" under 42 C.F.R. § 414.46 because they were "distracted" during a portion of certain surgeries. (*See* FAC ¶¶ 8–10, 190, 256.) But, the regulation does not address "distractions" at all. Instead, it states as follows:

> ***Anesthesia time means the time during which an anesthesia practitioner is present with the patient***. It starts when the anesthesia practitioner begins to prepare the patient for anesthesia services and ends when the anesthesia practitioner is no longer furnishing anesthesia services to the beneficiary, that is, when the beneficiary may be placed safely under postoperative care. Anesthesia time is a continuous time period from the start of anesthesia to the end of an anesthesia service. In counting anesthesia time, the anesthesia practitioner can add blocks of anesthesia time around an interruption in anesthesia time as long as the anesthesia practitioner is furnishing continuous anesthesia care within the time periods around the interruption.

42 C.F.R. § 414.46(a)(3) (emphasis supplied). The language could not be more plain. Time that an anesthesia provider is "present with the patient" during anesthesia is "anesthesia time."

In the face of that language, Relator fails to allege that the Physician Defendants or other MWA anesthesiologists were not present with the patient in the operating room during surgeries for which they submitted claims to government payors. Just the opposite, regardless of any alleged "distraction," the FAC pleads that the Physician Defendants and other MWA anesthesiologists ***remained fully present in the operating room*** during the surgeries in question.[3] (*See* FAC ¶¶ 157–

[3] The FAC describes only *one* instance when *one* anesthesiologist—Dr. Debenham—allegedly left the operating room during surgery. (*See* FAC ¶ 157.) But, even assuming Dr. Debenham did step out of the operating room, he may still have been "present" within the meaning of the regulation. *See, e.g.*, 42 C.F.R. § 415.110(a) (physician can be "physically present and available for immediate diagnosis and treatment of emergencies" for up to "four concurrent anesthesia services" in the context of medically directed services). At any rate, Relator does ***not*** claim that this occurred

179.) As a result, the FAC does not plausibly allege any false statements based on 42 C.F.R. § 414.46 in connection with any claim for government reimbursement.

Relying on purported "expert" opinion[4] and non-binding commentary from professional organizations, Relator argues—contrary to the regulation's plain language—that anesthesiologists cannot claim time in which they are "distracted" as "anesthesia time," even if they are present with the patient. (*See, e.g.*, FAC ¶¶ 13–15, 89, 92, 94-100.) The regulation, however, plainly provides that: "***Anesthesia time means the time during which an anesthesia practitioner is present with the patient***." 42 C.F.R. § 414.46(a)(3) (emphasis supplied). While "anesthesia time" must be a "continuous time period," and "an interruption in anesthesia time" cannot be billed, the regulation's plain definition of "anesthesia time" compels the conclusion that "*continuous*" anesthesia time means continuous time *in the presence of the patient*, and an "interruption in anesthesia time" occurs when an anesthesiologist is *not* present with the patient. Because the language is clear, the Court need look no further than the text itself to reject Relator's theory of falsity. *See Scalia v. Wynnewood Refining Co., LLC*, 978 F.3d 1175, 1181 (10th Cir. 2020)

during surgery involving a Medicare, Medicaid, or TRICARE patient or that any Defendant submitted a claim for government reimbursement for this surgery. (*See* FAC ¶ 157.)

[4] The Court should ignore the two "expert" reports appended to the FAC. *See, e.g.*, *United States v. Comstor Corp.*, 308 F. Supp. 3d 56, 69 n.4 (D.D.C. 2018) (refusing to consider report attached to complaint that did not address "factual matter" pertinent to the case); *In re Under Armour Sec. Litig.*, 409 F. Supp. 3d 446, 454-55 (D. Md. 2019) ("Expert opinions generated for purposes of supporting Plaintiffs' theories in … their complaint do not warrant the assumption of truth."). The Busch report (FAC, Ex. 2) is especially irrelevant because it mostly consists of the legal opinions of a non-lawyer about the meaning of the relevant anesthesia regulations. *See Comstor Corp.*, 308 F.3d at 69 n.4 (refusing to consider a report attached to the complaint in which a purported expert offered an "interpretation of … regulations" because "interpreting the relevant law and regulations is the job of the Court"). That Relator felt the need to attach such a report is a telling indication of the lack of any other authority supporting his novel reading of the relevant regulations.

("[W]hen interpreting [a] regulation, we begin by examining the plain language of the text, giving each word its ordinary and customary meaning. If, after engaging in this textual analysis, the meaning of the regulation[] is clear, our analysis is at an end, and we must enforce the regulation[] in accordance with [its] plain meaning." (internal quotation marks omitted)).

Nor is Relator's reading of the regulation even remotely workable. If Relator's interpretation were correct, an anesthesiologist would have to track and deduct *any* time when he or she was "distracted" during surgery—or else face the prospect of civil and criminal penalties. (*See* FAC ¶ 89 ("[T]he anesthesiologist must maintain a constant state of situational awareness.").) One wonders just what could qualify as a "distraction." Need an anesthesiologist deduct time for listening to music during surgery? For chatting with a nurse or other clinician? For daydreaming about weekend plans? Relator offers no proposal for how courts would draw the relevant lines, and he has even less to say about how those lines could possibly be *enforced*. It should come as no surprise, therefore, that the FAC points to no case law or authoritative guidance that in any way supports his novel understanding of the relevant regulations.

The FAC separately contends that MWA submitted factually false claims because the Physician Defendants and other MWA anesthesiologists supposedly did not "personally perform" the anesthesia services at issue. (*See* FAC ¶¶ 10, 88, 106, 120–21, 150, 152, 188–91.) Again, the relevant regulations contradict Relator's argument. As the FAC itself recognizes, "personally performed" anesthesia services designate the *identity* and *role* of the provider who rendered the services. (*See* FAC ¶ 120.) *See also* 42 C.F.R. § 414.46(c), (d), (f) (distinguishing "personally performed" services from services "medically directed by" a particular physician but performed by others). Anesthesia services are "personally performed under ***any*** of [six listed]

circumstances," including when a "physician ***performs the entire anesthesia service alone***." 42 C.F.R. § 414.46(c) (emphasis supplied). Because the FAC does not allege that anyone else performed an anesthesia service in a particular physician's absence, there can be no question that the anesthesia services at issue were, in fact, personally performed. (*See, e.g.,* FAC ¶ 88 (admitting that "the only anesthesia provider in the operating room" during the surgeries at issue was the allegedly distracted anesthesiologist). Any statements to that effect made by any Defendant were, therefore, not factually false, and Relator's factual falsity theories fail.

B. The FAC's Allegations Do Not Plead a Plausible Theory of Legal Falsity.

Nor does the FAC plead legal falsity. Legal falsity may take two forms, but both require a false certification. *See Polukoff,* 895 F.3d at 741. "An express false certification theory applies when a government payee falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." *Id.* "'[T]he pertinent inquiry for implied-false-certification claims is … whether, through the act of submitting a claim, a payee knowingly and falsely implied that it was entitled to payment." *Id.* For implied false certification, two conditions must be satisfied: "first, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Escobar*, 136 S. Ct. at 2001.

If Relator offers a legal falsity theory based on alleged violations of 42 C.F.R. § 414.46, that theory fails for the reasons discussed above. Simply put, the FAC does not plausibly allege that MWA or the Physician Defendants *falsely* certified compliance with the regulation because the FAC does not plausibly allege any *violations* of the regulation in the first place.

Relator's other legal falsity theory is that the "distracted" anesthesia services were not "reasonable and necessary," as required for every item or service reimbursed by Medicare. *See* 42 U.S.C. § 1395y(a)(1)(A). This argument fares no better because—once again—Relator misconstrues the nature of the requirement. In the context of government reimbursement, "the requirement that a service be reasonable and necessary generally pertains to the ***selection*** of the particular procedure and ***not to its performance***." *Mikes v. Straus*, 274 F.3d 687, 701 (2d Cir. 2001) (emphasis supplied), *abrogated on other grounds by Escobar*, 136 S. Ct. 1989. In other words, if the services at issue are appropriate to treat the patient's condition, then they are reasonable and necessary for purposes of Medicare and the FCA—regardless of whether a relator disagrees with how those services are performed. And for good reason. "[P]ermitting *qui tam* plaintiffs to assert that defendants' quality of care failed to meet medical standards would promote federalization of medical malpractice, as the federal government or the *qui tam* relator would replace the aggrieved patient as plaintiff." *Id.* at 700. That is neither the intent, nor the effect, of the FCA. *See, e.g.*, *Escobar*, 136 S. Ct. at 2004 (noting that an FCA case "centers on allegations of fraud, not medical malpractice"); *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1221 (10th Cir. 2008) ("[S]tate tort law"—rather than the FCA—"remains a powerful incentive for [a] hospital to provide quality care."); *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 467-68 (6th Cir. 2011) ("[R]equesting payment for tests that allegedly did not comply with a particular standard of care does not amount to a 'fraudulent scheme' actionable under the FCA.").

To argue otherwise, Relator latches onto out-of-context language from the Tenth Circuit's decision in *Polukoff*, which suggests that medical services may not be reasonable and necessary if they are not "[f]urnished in accordance with accepted standards of medical practice for the

diagnosis or treatment of the patient's condition or to improve the function of a malformed body member." *Polukoff*, 895 F.3d at 736 (quoting Medicare Program Integrity Manual § 13.5.1, Centers for Medicare and Medicaid Services (2015)). This statement, however, was *dicta* at best, because *Polukoff* concerned the appropriate ***selection*** of services, not their quality.[5] Unlike this case, *Polukoff* did not involve *quality-of-care* allegations relating to an otherwise reasonable and necessary service, and thus *Polukoff* would provide no support for Relator's theory.[6]

Nor can the sub-regulatory guidance quoted in *Polukoff* save Relator's legal falsity theory. As noted above, the sentence in *Polukoff* on which Relator relies quoted from the Medicare Program Integrity Manual. *Polukoff*, 895 F.3d at 736. But, Medicare manuals—which are not enacted through notice-and-comment rulemaking—do not carry the force of law or impose binding requirements for payment. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1810, 1816–17 (2019) (holding that "interpretive" agency guidance that has not undergone formal notice-and-comment rulemaking—such as the guidance found in the Medicare Program Integrity Manual—cannot validly establish a "substantive legal standard" under the Medicare Act).[7] Thus, violations

[5] The services at issue in *Polukoff* were patent foramen ovale ("PFO") closures provided to patients with migraine headaches. 895 F.3d at 736. Because Medicare and Medicaid would not pay for PFO closures to treat migraines, the physician in *Polukoff* allegedly represented—falsely—that the PFO closures were performed to treat recurring strokes. The Tenth Circuit found these facts sufficient to plead falsity. *See id.* at 737, 743.

[6] Relator makes no effort to hide the fact that his FCA claims are premised on alleged quality-of-care shortcomings, as the FAC is replete with quality-of-care allegations. (*See, e.g.,* FAC ¶ 5 ("This substandard medical practice turned into actionable fraud when Defendants billed the government for it."), ¶ 6 ("Defendants violated the 'reasonable and necessary' requirement by furnishing anesthesia services in a way that … deviated substantially from accepted standards of medical practice ….").

[7] *Allina* contemplates a different result if the "*statute* itself" sets forth the relevant substantive legal standard. *Id.* at 1816 (emphasis in original). That logic cannot apply to Relator's argument here

of a manual provision—without more—do not support FCA liability under a theory of legal falsity.[8] *See, e.g.*, *U.S. ex rel. Polansky v. Exec. Health Res., Inc.*, 422 F. Supp. 3d 916, 931 (E.D. Pa. 2019) (citing *Allina* and concluding that "because the reimbursement standard applicable to [the relator's] claims was contained in agency manuals that had not been promulgated pursuant to notice and comment … Defendant could not have violated the FCA").[9]

C. Relator Fails to Plead Facts Sufficient to Support a "Worthless Services" Theory.

Besides factual and legal falsity, some courts have recognized that an FCA claim may also be based on a "worthless services" theory. *See Dental Dreams*, 2016 WL 9777254, at *9. "A worthless services theory is based on 'the knowing request for federal reimbursement for a procedure with no medical value.'" *Id.* (quoting *Mikes*, 274 F.3d at 702). Here, however, the Court need not decide whether a "worthless services" theory is viable because, even assuming it were, Relator has not pleaded facts to support it.

For courts recognizing a worthless services theory, it is not enough that the services in question fell short of professional standards. To state a cognizable claim under such a theory, the services must be "so deficient as to be worthless." *Id.* Allegations of negligence are insufficient,

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because the statutory phrase "reasonable and necessary" has long been understood by courts ***not*** to encompass the manner in which services are performed. *See, e.g.*, *Mikes*, 274 F.3d at 701.

[8] The FAC also cites alleged violations of Medicare conditions of participation as a potential basis for a legal falsity theory. But, as the FAC acknowledges (*see* FAC ¶¶ 130-138), those conditions of participation apply only to *hospitals* and thus cannot support the falsity element of Relator's FCA claims against MWA or the Physician Defendants. *See* 42 C.F.R. § 482.1(b).

[9] Indeed, the U.S. Department of Justice has expressly disclaimed reliance on them as a substantive basis for imposing FCA liability. *See* U.S. Dep't of Justice, Justice Manual § 1-20.100 (2018) ("Criminal and civil enforcement actions brought by the Department must be based on violations of applicable legal requirements, not mere noncompliance with guidance documents issued by federal agencies, because guidance documents cannot themselves create binding requirements….").

as are claims that the services provided "were worth less than the services paid for." *Id.*; *see also U.S. ex rel. Absher v. Momence Meadows Nursing Ctr., Inc.*, 764 F.3d 699, 710 (7th Cir. 2014) ("It is not enough … that the defendant provided services that are worth some amount less than the services paid for" because "[s]ervices that are 'worth less' are not 'worthless'").

Here, although Relator claims that the anesthesia services provided by the allegedly distracted anesthesiologists strayed from best practices or relevant professional guidelines, Relator does not allege that the services lacked any value. In fact, the FAC makes clear that the services ***did*** have value—it confirms that the relevant patients received anesthesia, and it does not dispute that the anesthesia was effective. (*See* FAC ¶¶ 156–82.) Nor does the FAC allege any patient harm. Thus, even assuming anesthesiologists were "distracted" while providing anesthesia, the FAC makes no *plausible* allegation that the services were worthless. *See, e.g.*, *Dental Dreams*, 2016 WL 9777254, at *9 ("[T]he specific facts [pleaded] do not plausibly suggest … the procedure had no medical value and that Defendants knew the procedure was so deficient as to amount to no procedure at all. Rather, the allegations suggest a service of poor quality, and negligence is not sufficient."); *U.S. ex rel. Blundell v. Dialysis Clinic, Inc.*, 2011 WL 167246, at *21 (N.D.N.Y. Jan. 19, 2011) (unpublished) ("[P]laintiff challenges the quality of care arguing that defendant's services did not conform with [regulatory guidelines]. This allegation is not the 'equivalent of no performance at all' and thus, does not fit within the worthless services category.").

For all these reasons, Relator has failed to plausibly plead the falsity elements of any of his FCA claims against MWA or the Physician Defendants, and those claims should be dismissed.

II. The FAC Fails to Plead Fraud with Particularity.

Even if Relator had pleaded a plausible falsity theory, his FCA allegations would still fail

because they lack the particularity demanded by Rule 9(b), which requires an FCA relator to plead with particularity *both* the details of the alleged underlying fraud scheme *and* the submission of specific false claims to the government. *Sikkenga*, 472 F.3d at 727. To plead a fraud scheme with particularity, "[a]t a minimum," a relator must "set forth the 'who, what, when, where and how' of the alleged fraud," including the "time, place, and contents" of the relevant false representation, "the identify of the party making the false statements and the consequences thereof." *Id.* Because the submission of a false claim to the government is "a central element of every [FCA] case," however, allegations covering the particulars of the underlying fraud scheme must also be "linked to allegations, stated with particularity, of the actual false claims submitted to the government." *Id.* The Tenth Circuit has emphasized that it is not enough for an FCA relator "merely to describe a private scheme in detail but then to allege simply and without any stated reason for his belief that claims requesting illegal payment must have been submitted, were likely submitted or should have been submitted to the Government." *Id.*; *see also, e.g.*, *U.S. ex rel. Wynne v. Blue Cross and Blue Shield of Kan., Inc.*, 2006 WL 1064108, at *8 (D. Kan. Apr. 21, 2006) (unpublished) ("The fact that plaintiff has described procedures that might have allowed the defendant to submit false claims does not allow this court to speculate that false claims were in fact submitted.").

Adequately pleading the submission of false claims requires at least some "details that identify particular false claims for payment that were submitted to the government," such as "the dates of the claims, the content of the forms or the bills submitted, their identification numbers, the amount of money charged to the government, the particular goods and services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices." *Sikkenga*,

472 F.3d at 727. While these details are not a "checklist of mandatory requirements," an FCA complaint must supply at least "*some* of this information, for at least *some* of the claims … in order to satisfy Rule 9(b)." *Id.* (emphasis supplied). The FAC fails to satisfy these requirements.

A. The FAC Does Not Plead FCA Claims Against the Physician Defendants with Particularity.

The FAC's allegations relative to the Physician Defendants do not come close to complying with Rule 9(b). The *only* particular allegations about the Physician Defendants are set forth in Paragraphs 156 through 161, which follow the same formula for each physician: (1) an allegation that the physician "regularly," "frequently," or "routinely" used a personal electronic device in the OR during a multi-year period; (2) perhaps a brief description of one instance in which that physician was distracted; and (3) an allegation that the physician falsely recorded "the entire surgery time as anesthesia time." Nowhere in these paragraphs, however, does Relator identify a specific *date* on which this alleged conduct took place, a specific *patient* who was affected by the conduct, or a specific *claim* submitted to the government. For that matter, there is no specific allegation that the supposedly "distracted" services described in these paragraphs led to claims *at all*, much less that any of the claims were submitted to a federal healthcare program, rather than a private insurer. And, given that the FAC does not describe any claims resulting from the Physician Defendants' services in the first place, the FAC certainly does not identify any of the claim-specific details described in *Sikkenga* as necessary to satisfy Rule 9(b). *See Sikkenga*, 472 F.3d at 727; *see also, e.g.*, *U.S. ex rel. Sharp v. E. Okla. Orthopaedic Ctr.*, 2009 WL 499375, at *9 (N.D. Okla. Feb. 27, 2009) (unpublished) (dismissing FCA allegations that were "not tied to any particular patient, chart number, or claim"). In short, as to the Physician Defendants, Relator has "allege[d]

at best the existence of a general scheme or methodology by which [they] could have violated the [FCA]," which is "simply insufficient under Rule 9(b)." *U.S. ex rel. Feaster v. Dopps Chiropractic Clinic, LLC*, 2015 WL 6801829, at *5 (D. Kan. Nov. 5, 2015) (unpublished).

Nor can Relator rely on general allegations lodged against MWA or its anesthesiologists *as a group* to plead viable FCA claims against the individual Physician Defendants. When multiple defendants are involved in an FCA case, "[i]t is particularly important … that the complaint make clear exactly *who* is alleged to have done *what* to *whom*, to provide each individual with fair notice as to the basis of the claims against him or her." *U.S. ex rel. Brooks v. Stevens-Henager Coll.*, 305 F. Supp. 3d 1279, 1292 (D. Utah 2018) (internal quotation marks omitted). For that reason, "[a] complaint must make specific allegations against each individual defendant," which "includes allegations as to what particular claims were allegedly submitted by [the defendant], the content of any such false claims, and who precisely was involved in the fraudulent activity." *U.S. ex rel. Bender v. N. Am. Telecomms., Inc.*, 686 F. Supp. 2d 46, 50-51 (D.D.C. 2010) (internal quotation marks omitted). Because the FAC fails to identify even a single patient treated by any of the Physician Defendants and does not describe any claim for payment associated with care that any of them provided, Relator's claims against the Physician Defendants must be dismissed. *See, e.g.*, *United States v. Public Warehousing Co., K.S.C.*, 242 F. Supp. 3d 1351, 1359-61 (N.D. Ga. 2017) (Even where general allegations are sufficient to state a claim, the failure to plead allegations against the individual defendants with particularity requires dismissal.).

B. The FAC Does Not Plead FCA Claims Against MWA with Particularity.

The FAC likewise falls short because it fails to identify representative false *claims* made to government healthcare programs, rather than allegedly distracted *services*. After all, the

purported "examples of false claims" for physician services described at Paragraph 183 identify patients, dates of service, and CPT codes presumably based on the procedure, but do not identify any amount billed to the government, any claim number, the date on which any claim was actually submitted, or any person responsible for submitting any claim. These examples supply hardly any of the *claim*-specific details identified in *Sikkenga*. *See* 472 F.3d at 727. As other courts have held in similar circumstances, Rule 9(b) requires much more. *See, e.g.*, *U.S. ex rel. Ernst v. HCA Healthcare, Inc.*, 2020 WL 6868775, at *4 (D. Kan. Nov. 23, 2020) (unpublished) (allegations were insufficient under Rule 9(b) where, as in this case, the relator "ha[d] not alleged the dates of submission of claims to the government, the claim numbers, the amounts of claims, or the identify of any person involved in the submission of the claims"); *U.S. ex rel. Jallali v. Sun Healthcare Grp.*, 2015 WL 10687577, at *5-6 (S.D. Fla. Sep. 17, 2015) (unpublished) (not enough to identify specific patient charts and billing codes because the relator simply "assum[ed] that [certain] charts and codes ultimately translated into particular bills … submitted to the government").

In addition to failing to plead actual claims, Relators' allegations regarding MWA's alleged role fare no better. Unlike with the Physician Defendants, Relator alleges three specific instances in which MWA supposedly billed for anesthesia services provided by distracted anesthesiologists. (*See* FAC ¶¶ 163-182.) But, while the FAC provides some detail with respect to the three examples, Relator never identifies the allegedly distracted anesthesiologist. (*See, e.g.*, FAC ¶ 165 ("Throughout the four-hour surgery, *the anesthesiologist* was consumed by the Internet." (emphasis supplied).) In fact, with respect to two of the three "examples" (FAC ¶¶ 163-71 ("Example 1") and ¶¶ 176-82 ("Example 3), the FAC fails to allege that the unnamed anesthesiologist was even employed by MWA. These are critical omissions. Because Rule 9(b)

requires a relator to plead with particularity, among other elements, "the *who*" of the alleged fraudulent scheme, *see Sikkenga*, 472 F.3d at 727, the FAC's failure to link particular false claims to particular MWA-employed anesthesiologists dooms the FCA claims against MWA. *See, e.g.*, *U.S. ex rel. Barrick v. Parker-Migliorini Int'l, Inc.*, 2015 WL 9412537, at *4 (D. Utah Dec. 22, 2015) (unpublished) ("Rule 9(b) requires that a complaint set forth the identity of the party making the false statements, that is, which statements were allegedly made by whom"). As another district court within this district explained in *Barrick*, particularly when a defendant entity is "made up of hundreds, if not thousands of employees," Rule 9(b) "[a]t a minimum … demands that [a relator] identify the employee or employees responsible for the alleged false claims under the FCA." *Id.*

III. The FAC Fails to Adequately Plead the Materiality Element of Any FCA Claim.

The FAC also fails to allege that any false statements made by MWA or the Physician Defendants were material to payment. Materiality is a "rigorous" and "demanding" FCA element. *Escobar*, 136 S. Ct. at 1996, 2003. As *Escobar* explains, any analysis of the FCA's materiality element must "look[] to the effect of the likely or actual behavior of the recipient of the alleged misrepresentation." *Id.* at 2002. That the government may have "designate[d] compliance with a particular statutory, regulatory or contractual requirement as a condition of payment" is not enough to make a misrepresentation about compliance material, "[n]or is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance." *Id.* Instead, "the sine qua non of materiality is some quotient of potential influence on the decisionmaker." *Janssen*, 949 F.3d at 540. Thus, "if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material." *Escobar*, 136 S. Ct. at 2003.

Here, Relator offers precious little to suggest that the purported "distractions" described in the FAC were material to the government's payment of claims for anesthesia services. The FAC makes the purely conclusory allegation that "[n]o reasonable government would … pay" for distracted services, but it pleads no factual allegations to support that statement. (FAC ¶ 220.) The FAC also asserts that "[t]he anesthesiology billing regulation establishes conditions of payment" (FAC ¶ 221), but that is *precisely* the type of label-driven allegation the Supreme Court rejected as insufficient to plead materiality in *Escobar*. *See Escobar*, 136 S. Ct. at 2003 ("A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment."). While the FAC offers Relator's opinion that the alleged regulatory violations here "go to the essence of the bargain" and constitute "grave misconduct" (FAC ¶ 223), it fails to point to any statement, commentary, or guidance from the government that support that view. *Cf. Janssen*, 949 F.3d at 543 ("[I]n the complex matrix of Medicare reporting and reimbursement, such broad appeals to the importance of accurate reporting cannot clear the rigorous materiality hurdle."). Finally, while the FAC cites examples of the government generally auditing anesthesia services or "enforc[ing] anesthesia payment rules," *none* of the examples cited in the FAC have anything to do with distractions in the operating room. (*See* FAC ¶¶ 225-226).

In fact, Relator does not point to a single instance—anywhere in the country and in the entire history of the Medicare and Medicaid programs—where the government has *ever* denied payment for anesthesia services because an anesthesiologist was "distracted" while providing the services. The FAC does not even allege that the government has denied or sought to recoup payment to any of the Defendants, despite explicitly being on notice of Relator's allegations at

least since the original complaint was filed more than a year ago. *See, e.g.*, *Janssen*, 949 F.3d at 542 (stating that the government's "inaction in the face of detailed allegations" of fraud "suggest[ed] immateriality"); *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) ("The fact that CMS has not denied reimbursement … in the wake of [FCA] allegations casts serious doubt on the materiality of the fraudulent representations."). Moreover, the government's decision not to intervene in this litigation is itself at least some indication that it does not attach any particular importance to the alleged regulatory violations. *See, e.g.*, *U.S. ex rel. Petratos v. Genentech, Inc.*, 855 F.3d 481, 490 (3d Cir. 2017) (citing the fact that "the Department of Justice has … declined to intervene" as one reason for affirming dismissal of FCA claims for failure to plead materiality).

In sum, Relator has not come close to offering well-pleaded factual allegations that would satisfy the FCA's "rigorous" and "demanding" materiality element. All of his FCA claims should be dismissed on that basis. *See Escobar*, 136 S Ct. at 2004 n.6 ("We reject [the] assertion that materiality is too fact intensive for courts to dismiss [FCA] cases on a motion to dismiss ….").

IV. The FAC Lacks Sufficient Allegations of Scienter.

The FAC also lacks adequate allegations to support the FCA's scienter element. FCA liability applies only when a defendant "knowingly" violates the law, *see* 31 U.S.C. § 3729(a)(1), which means that the defendant "has 'actual knowledge of the information,' 'acts in deliberate ignorance of the truth or falsity of the information,' or 'acts in reckless disregard for the truth or falsity of the information.'" *Escobar*, 136 S. Ct. at 1996 (quoting 31 U.S.C. § 3729(b)(1)(A)). Like materiality, the FCA's scienter element is "rigorous." *Id.* at 2002. Negligence is not enough, nor will merely conclusory allegations of intentional or reckless misconduct suffice. *See U.S. ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 949 (10th Cir. 2008). Moreover, the FCA's scienter

standard can only be met when a defendant adopts an objectively unreasonable interpretation of clearly established legal requirements. *See, e.g., U.S. ex rel. Schutte v. SuperValu Inc.*, 2021 WL 3560894, at *8 (7th Cir. Aug. 12, 2021) (relying on the U.S. Supreme Court's decision in *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007), and concluding that the failure to meet the objective scienter standard precludes a finding that defendant acted knowingly under the FCA).[10]

MWA and the Physicians Defendants submit that the meaning of the requirements of 42 C.F.R. § 414.46, which the FAC alleges were violated, is clear based on the regulation's plain text—namely that it requires an anesthesiologist "to be present with the patient" when providing anesthesia services and does not require discounting of time associated with subjective distractions. At a minimum, however, that interpretation is an *objectively reasonable* one. Thus, even if Relator were to offer a different interpretation of the regulation, the FAC cannot plausibly plead scienter because the FAC alleges conduct in accordance with an objectively reasonable interpretation of the plain text of the regulation at issue. *See Schutte*, 2021 WL 3560894, at *12; *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879 (8th Cir. 2016) ("[A]n FCA defendant's reasonable interpretation of an ambiguous regulation belies the scienter

[10] While the Tenth Circuit has not expressly adopted *Safeco*'s standard with respect to the FCA, all seven courts of appeal that have considered *Safeco* in the FCA context, including most recently the Seventh Circuit in *Schutte*, have concluded that *Safeco*'s objective standard applies to the FCA's scienter requirement. *See U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 290-91 (D.C. Cir. 2015); *U.S. ex rel. Streck v. Allergan, Inc.*, 746 F. App'x 101, 106 (3d Cir. 2018); *U.S. ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017); *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 879-80 (8th Cir. 2016); *see also U.S. ex rel. Complin v. N.C. Baptist Hosp.*, 818 F. App'x 179, 184 & n.6 (4th Cir. 2020); *U.S. ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 657-58 & n.39 (5th Cir. 2017). Even without relying on *Safeco*, the Tenth Circuit has indicated that "legal uncertainty preclude[s] a finding of scienter under the FCA." *Pack v. Hickey*, 776 F. App'x 549, 557 (10th Cir. 2019).

necessary to establish a claim of fraud under the FCA." (quotation marks and citation omitted)).[11]

Relators' purported factual allegations to support scienter mostly consist of conclusory statements that the Defendants "should be presumed to know" that their claims were ineligible for reimbursement, supposedly because the relevant regulations and guidance are "clear." (FAC ¶¶ 205, 207.) But, the Court may not infer scienter from the alleged regulatory violation itself. *See Complin*, 818 F. App'x at 184 ("[E]ven assuming non-compliance with [a regulation] … that would not by itself give rise to an inference of scienter."). Relator otherwise alleges only that he "expressed his concerns about the anesthesiologists' pervasive use of PEDs" during a single meeting nearly fifteen years ago. (*See* FAC ¶¶ 209-210.) Relator does not elaborate on the "concerns" he expressed, and thus this allegation does not show that any Defendant was put on notice of potential regulatory violations or the submission of false claims, rather than generic quality-of-care concerns.[12] Relator's remaining allegation about "one-on-one conversations" with unnamed anesthesiologists "over the years" (FAC ¶ 212) is even more vague and does not suffice. *See, e.g.*, *U.S. ex rel. Simpson v. Leprino Foods Dairy Prods. Co.*, 2018 WL 1375792, at *2 (D. Colo. Mar. 19, 2018) (unpublished) ("Although Rule 9(b) permits intent, knowledge, or condition of mind to be averred generally, courts have repeatedly required plaintiffs to plead the … factual basis that gives rise to a strong inference of fraudulent intent.").

[11] Although both *Schutte* and *Donegan* were decided at summary judgment, the application of the standard set forth in *Safeco* as applied to FCA claims is a question of law. *See, e.g., U.S. ex rel. Sheldon v. Forest Labs.*, 499 F. Supp. 3d 184, 212 (D. Md. 2020).

[12] Even if this allegation otherwise supported an inference of scienter, Relator identifies only *one* of the Physician Defendants as having attended the meeting. *See United States v. Strock*, 982 F.3d 51, 66 (2d Cir. 2020) (FCA complaint "must plead facts supporting scienter as to each defendant").

V. The FAC Does Not Plead a Viable "Reverse" False Claims Theory.

Relator also asserts claims under the FCA's so-called "reverse" false claims provision, 31 U.S.C. § 3729(a)(1)(G). This provision "reverses the typical claim under the False Claims Act: instead of creating liability for wrongfully *obtaining* money from the government, the reverse-false-claims provision creates liability for wrongfully *avoiding* payments that should have been made to the government." *U.S. ex rel. Barrick v. Parker-Migliorini Int'l, LLC*, 878 F.3d 1224, 1230 (10th Cir. 2017). A violation occurs when a defendant "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G).

The FAC fails to plead a plausible claim under the reverse false claims provision for many reasons. Most notably, however, Relator's reverse false claims allegations are redundant of his traditional false claims theory, as he alleges that Defendants submitted or caused to be submitted false claims for payment, and then violated the reverse false claims provision by failing to return the resulting payments. As "numerous courts" have held, however, "a relator cannot establish a reverse false claim based on the alleged retention of money received from the submission of a false claim." *U.S. ex rel. Lovato v. Kindred Healthcare, Inc.*, 2020 WL 9160872, at *21 (D. Colo. Dec. 14, 2020) (unpublished); *see also, e.g.*, *U.S. ex rel. Tra v. Fesen*, 403 F. Supp. 3d 949, 965 (D. Kan. 2019) ("[S]ection 3729(a)(1)(G) cannot be construed so as to be redundant with false claims and records under subsections (a)(1)(A) and (a)(1)(B)."). After all, "if the conduct that gives rise to a traditional presentment or false statement action also satisfies the demands of section 3729(a)(1)(G), then there would be nothing 'reverse' about an action brought under that latter section of the FCA." *Lovato*, 2020 WL 9160872, at *21.

To avoid this problem, Relator half-heartedly tries to pin reverse false claims liability to his allegation that he "raised concerns" to "Defendants' leadership as early as 2007," which he argues triggered a duty for Defendants to exercise "reasonable diligence" to determine whether they had received overpayments from the government. (FAC ¶¶ 242-43.) But, the FAC does not allege that the "concerns" he expressed related to *payments*; it alleges they related to *patient safety*. (*See id.* ¶ 242 (alleging that Dr. Khoury "cautioned Defendants that the use of PEDs during surgery was a dangerous distraction.").) Given the novel nature of Relator's falsity theory, this allegation certainly does not plausibly suggest that any repayment obligation was an "established duty," rather than "merely potential or contingent." *Barrick*, 878 F.3d at 1231.[13]

VI. The FAC Does Not Plausibly Allege an FCA Conspiracy.

The problems with Relator's other FCA claims are also fatal to his conspiracy claim, because without a viable underlying theory of an FCA violation, an FCA conspiracy claim fails. *See, e.g.*, *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 459 F. Supp. 2d 1081, 1091 (D. Kan. 2006); *Singer v. Progressive Care, SC*, 202 F. Supp. 3d 815, 827-28 (N.D. Ill. 2016).

CONCLUSION

For the reasons above, MWA and the Physician Defendants respectfully request that this Court dismiss with prejudice[14] the claims asserted in Relator's FAC.

Dated this 31st day of August 2021.

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[13] Relator's reverse false claims allegations also violate Rule 9(b) for the same reasons discussed above relative to traditional FCA liability. That is particularly true for the five Physician Defendants, who Relator nowhere specifically alleges were on notice of potential overpayments or had any ability to return overpayments received by their employer.

[14] Dismissal should be with prejudice because Relator has already amended once and any further amendment would be futile. *See Bylin v. Billings*, 568 F.3d 1224, 1229 (10th Cir. 2009).

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CERTIFICATE OF SERVICE

I hereby certify that on August 31, 2021, I electronically filed the foregoing document with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to the following, and/or served the foregoing via U.S. Mail and electronic mail upon:

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